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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/580,556	05/26/2006	Sang Yup Lee	4240-142	1480

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INTELLECTUAL PROPERTY / TECHNOLOGY LAW
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EXAMINER

MEAH, MOHAMMAD Y

ART UNIT	PAPER NUMBER
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1652

MAIL DATE	DELIVERY MODE
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08/23/2007

PAPER

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary	Application No. 10/580,556	Applicant(s) LEE ET AL.	
	Examiner Mohammad Meah	Art Unit 1652	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 30 May 2007.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-35 is/are pending in the application.
- 4a) Of the above claim(s) 1,3-7,10-30 and 33-35 is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 2,8,9,31 and 32 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
 2. ☐ Certified copies of the priority documents have been received in Application No. _____.
 3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- * See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|--|---|
| 1) <input type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413) |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | Paper No(s)/Mail Date. _____ |
| 3) <input checked="" type="checkbox"/> Information Disclosure Statement(s) (PTO/SB/08) | 5) <input type="checkbox"/> Notice of Informal Patent Application |
| Paper No(s)/Mail Date <u>5/26/07, 7/31/06</u> | 6) <input type="checkbox"/> Other: _____ |

DETAILED ACTION

Claims 1-35 are pending.

Election/Restriction

During preliminary amendment of this application, the applicant, on date 5/3/2007 elected with traverse Group II (claims 2, 8-9, 31-32) for examination. The traversal is on the ground(s) that (1) the groups are not classified in separate class/subclass and therefore it is uncertain whether the claims grouped in different group are independent or distinct and (2) there is no undue burden on examining all groups. This is not found persuasive as explained bellow and therefore Groups I and III-XIII (claims 1, 3-7, 10-30, 33-35) of election/restriction-office action of date 4/30/2007 are withdrawn from further consideration pursuant to 37 CFR 1.142(b), as being drawn to nonelected Groups.

Applicants argument that the restriction is improper as the groups were not classified by class/subclass is not persuasive because this case is a 371 case in which PCT Rules of lack of unity apply. PCT Rule does not require class/subclass classification it require restriction based on special technical feature as explained in the 4/30/2007 office action. Therefore applicants' argument is moot. Therefore the restriction is maintained.

Applicants further argue that there would be no undue burden on the examiner to examine all the claims. This is not persuasive because while the search for each of these distinct groups would be overlapping it would not be coextensive. Art that applies for bacteria having gene encoding one protein may or may not apply to bacterium with different gene encoding different protein. Therefore the restriction is maintained.

The requirement is still deemed proper and is therefore made FINAL.

Priority

Acknowledgement is made of applicant's PCT priority date based on application filing date of 05/20/2004 of PCT/KR04/01210 and foreign applications Korea 10-2003-0084934 11/27/2003 and Korea 10-2004-0028105 04/23/2004,

281933 filed on 7/29/2003.

Claim Objections

Claim 2 are objected in reciting "--mutant which--" in line 1 and " - -and has the property- -" in line 3. These recitation should be corrected by reciting " - -mutant in which--" in line 1 and " - -and which has the property- -" in line 3. Appropriate correction is required.

Claim Rejections

35 U.S.C 112

The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

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Claims 2 and 32 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

Claim 2 - the recitation "high concentration" is confusing as it is unclear how high is it.

Claim 2 and 32 - the recitation "little other organic acids" is confusing as it is unclear how little these organic acids could be.

Claim Rejections

35 U.S.C 112

The following is a quotation of the first paragraph of 35 U.S.C. 112:

The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

Claims 2 and 31-32 are rejected under 35 U.S.C. 112, first paragraph, as containing subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention.

These claims are directed to any rumen mutant bacteria having disruption of any lactate dehydrogenase (ldhA), any pyruvate formate-lyase (pfl), any phosphotrans

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acetylase (pta) and any acetate kinase (ackA) so that it produces succinic acid in anaerobic conditions with production of very little other organic acids. The genus of rumen mutant bacterial strain having disruption of any lactate dehydrogenase (ldhA), any pyruvate formate-lyase (pfl), any phosphotransacetylase (pta) and any acetate kinase (ackA) is a large variable genus containing many strains from many sources. The specification does not teach the structures of all lactate dehydrogenase (ldhA), pyruvate formate-lyase (pfl), phosphotransacetylase (pta) and acetate kinase (ackA) of all rumen bacterial strain nor show that the ldhA, pfl, pta and ackA genes of the disclosed strain are representative of the genes of all disclosed rumen bacteria. The specification teaches only one mutant strain (as recited in claim 8 or 9). Therefore, one skilled in the art cannot reasonably conclude that the applicant had possession of the claimed invention at the time the instant application was filed. Applicant is referred to the revised guidelines concerning compliance with the written description requirement of U.S.C. 112, first paragraph, published in the Official Gazette and also available at www.uspto.gov.

Claims 2 and 31-32 are rejected under 35 U.S.C. 112, first paragraph, because the specification, while being enabling for rumen bacterial mutant strain comprising *Mannheimia* sp LPK7 or KCTC 10626BP (as recited in claims 8-9) does not reasonably provide enablement for any rumen mutant bacteria having disruption of any lactate dehydrogenase (ldhA), any pyruvate formate-lyase (pfl), any phosphotransacetylase (pta) and any acetate kinase (ackA) so that it produces succinic acid in anaerobic condition with production of very little other organic acids. The claims broadly recite

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any rumen mutant bacteria having disruption of any lactate dehydrogenase (ldhA), any pyruvate formate-lyase (pfl), any phosphotransacetylase (pta) and any acetate kinase (ackA) so that it produces succinic acid in anaerobic condition with production of very little other organic acids. The specification fails to describe how any rumen strain can be made by disrupting any lactate dehydrogenase (ldhA), any pyruvate formate-lyase (pfl), any phosphotransacetylase (pta) and any acetate kinase (ackA). The class of lactate dehydrogenase (ldhA), pyruvate formate-lyase (pfl), phosphotransacetylase (pta) and acetate kinase (ackA) genes recited in these claims is a large variable genus having any structure. The scope of the claims is not commensurate with the enablement provided by the disclosure with regard to disrupting any lactate dehydrogenase (ldhA), any pyruvate formate-lyase (pfl), any phosphotransacetylase (pta) and any acetate kinase (ackA) in any rumen bacteria. The specification discloses only one Rumen bacterial strain, *Mannheimia* sp LPK7 or KCTC 10626BP. As the structure of the lactate dehydrogenase (ldhA), pyruvate formate-lyase (pfl), phosphotransacetylase (pta) and acetate kinase (ackA) that needed to be disrupted structure of the claimed substances are not defined in any way nor defined in any way which rumen bacteria comprise said class of genes one of ordinary skill in the art would not be able to make and use any rumen bacteria without undue experimentation to first find which rumen bacteria in fact comprise said class of genes and then how to disrupt them without knowing their structure. Furthermore, the claimed class of rumen bacteria as well as lactate dehydrogenase (ldhA), pyruvate formate-lyase (pfl), phosphotransacetylase (pta) and acetate kinase (ackA) is likely to include many bacteria and many such genes, which one of ordinary skill in the art would be unable to make and use without undue

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experimentation, even if it was known or expected that the certain ruman bacteria having desirable lactate dehydrogenase (ldhA), pyruvate formate-lyase (pfl), phosphotransacetylase (pta) and acetate kinase (ackA) be within the scope of the claims.

Thus, applicants have not provided sufficient guidance to enable one of ordinary skill in the art to make and use the claimed invention in a manner reasonably correlated with the scope of the claims broadly including any rumen mutant bacteria having disruption of any lactate dehydrogenase (ldhA), any pyruvate formate-lyase (pfl), any phosphotransacetylase (pta) and any acetate kinase (ackA) from any source by any means so that it produces succinic acid in anaerobic cognition with production of very little other organic acids. The scope of the claims must bear a reasonable correlation with the scope of enablement (In re Fisher, 166 USPQ 19 24 (CCPA 1970)). Without sufficient guidance, making modified rumen strains having disruption of any lactate dehydrogenase (ldhA), any pyruvate formate-lyase (pfl), any phosphotransacetylase (pta) and any acetate kinase (ackA) from any source by any means so that it produces succinic acid in anaerobic cognition with production of very little other organic acids is unpredictable and the experimentation left to those skilled in the art is unnecessarily, and improperly, extensive and undue. See In re Wands 858 F.2d 731, 8 USPQ2nd 1400 (Fed. Cir, 1988).

Claims 8 and 9 are rejected under 35 U.S.C. 112, first paragraph, as containing subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention. Claims 8 and 9 recite novel mutant bacterial strains. Since the bacterial strains are essential to the claimed invention, it must

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be obtainable by a repeatable method set forth in the specification or otherwise be readily available to the public. The bacterial strains are not fully disclosed, nor have been shown to be publicly known and freely available. The enablement requirements of 35 U.S.C. § 112 may be satisfied by a deposit of the strains. The specification does not disclose a repeatable process to obtain the strains and it is not apparent if the strains are readily available to the public. Accordingly, it is deemed that a deposit of plasmid should have been made in accordance with 37 CFR 1.801-1.809.

It is noted that applicants have deposited the organisms but there is no indication in the specification as to public availability. If the deposit was made under the terms of the Budapest Treaty, then an affidavit or declaration by applicants, or a statement by an attorney of record over his or her signature and registration number, stating that the specific strain has been deposited under the Budapest Treaty and that the strain will be irrevocably and without restriction or condition released to the public upon the issuance of the patent, would satisfy the deposit requirement made herein.

If the deposit has not been made under the Budapest treaty, then in order to certify that the deposit meets the criteria set forth in 37 CFR 1.801-1.809, applicants may provide assurance or compliance by an affidavit or declaration, or by a statement by an attorney of record over his or her signature and registration number, showing that:

1. during the pendency of this application , access to the invention will be afforded to the Commissioner upon request;
2. all restrictions upon availability to the public will be irrevocably removed upon granting of the patent;

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3. the deposit will be maintained in a public repository for a period of 30 years or 5 years after the last request or for the effective life of the patent, whichever is longer; and

4. the deposit will be replaced if it should ever become inviable.

Conclusion

Claims 2, 8-9, 31-32 are rejected and no claim is allowable.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Mohammad Meah whose telephone number is 571-272-1261. The examiner can normally be reached on 8:30-5PM.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Ponnathapu Achutamurthy can be reached on 571-272-0928. The fax phone number for the organization where this application or proceeding is assigned is 703-872-9306.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

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